CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 6(b) **CX/FL 11/39/13**

JOINT FAO/WHO FOOD STANDARDS PROGRAM
CODEX COMMITTEE ON FOOD LABELLING

Thirty-ninth Session
Québec City, Canada, 9 – 13 May 2011

Labelling of Foods and Food Ingredients Obtained through Certain Techniques of Genetic Modification / Genetic Engineering

Report of the Facilitated Work Session

As agreed by the 38th Session of the Codex Committee on Food Labelling, a facilitated working session of the Codex Committee on Food Labelling was held in Brussels to further consider the matter of the labelling of foods derived through modern biotechnology. The meeting was chaired by Professor Josephine Nketsia-Tabiri from Ghana and facilitated by the Chair of the CCFL, Mr. Paul Mayers. Attached is the Chair's report of that facilitated meeting.

Governments and international organizations in Observer status with the Codex Alimentarius Commission wishing to submit comments on the on the options outlined in Appendix 3 of the report are invited to do so **no later than 4 March 2011** to:

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with a copy to the

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FACILITATED WORK SESSION

15/16 NOVEMBER 2010

BRUSSELS, BELGIUM

CHAIRPERSONS REPORT

1. A facilitated session of the Codex Committee on Food Labelling (CCFL) was held in Brussels, Belgium 15/16 November 2010 hosted by the European Union. This facilitated session, which had been agreed to by the 38th Session (May 2010) of the CCFL, was chaired by Ghana and facilitated by the chair of the CCFL with the goal of exploring the objectives of different delegations with regard to various versions of texts being considered under the CCFL agenda item dealing with the labelling of foods derived through modern biotechnology and to reconcile them in one text if possible. The session was attended by 71 participants representing 31 member governments and 10 international non-governmental organizations. A list of participants is attached as Appendix 1 to this report.
2. Prior to the facilitated session, a CL was circulated (CL2010/19-FL) inviting members and observers to provide in their comments a very clear rationale with respect to their objectives in relation to their proposals for changing text and that this would also be the approach in the facilitated work session because going back to the objectives would allow new options to be explored which could bridge the gap between different positions. Comments received in response to the CL will be circulated separately to all members and observer organizations as document CX/FL 11/39/13.
3. The facilitator began the session by reminding participants of the original charge to the CCFL from the 19th Session of the CAC to "provide guidance on how the fact that a food was derived from modern biotechnology could be made known to the consumer". He further noted that the purpose of the

discussions was not to defend a particular view or to criticize other views but rather to focus on objectives and the rationale behind positions. He also explained that the facilitation process would draw on "systems thinking" which is an approach that has had some success in seeking to improve/address "wicked problems". "Wicked problems" are characterized by ambiguity, uncertainty, several different perspectives on the issues and disagreement on goals and values. The approach involves a structured dialogue during which participants were expected to actively listen and be open to new ideas as all opinions were relevant. The chairperson would handle requests for the floor leaving the facilitator free to focus on exploring the rationale underlying interventions.

4. To start the process, each delegation was asked to complete the following two framing statements:

   Q.1 To be acceptable, a compromise text will need to reflect consideration….

   Q.2 In order to reduce the potential that a compromise text will be rejected, it should avoid…

5. Consideration of the various responses to the framing questions revealed several themes, the most prevalent being that it was important to include consideration that different approaches were used to label GM/GE foods but that texts had to be consistent with existing Codex texts.

6. Several delegations preferenced their responses by questioning whether the mandate given to the CCFL in 1991 was still relevant in the context of the current Codex environment. Some participants were of the view that the text should include reference to:

   - Purpose of the text
   - Clarity that the text could achieve
   - Method of production
   - Applicability to all foods (not just GM)
   - Recognition of substantial equivalence
   - Consideration of the mandate of Codex

7. It was further noted by a number of other participants that the text should avoid:

   - Being too prescriptive resulting in one approach being favoured over others
   - Introducing new principles in Codex
   - Referring or ratifying national standards/interests at the international level.
   - Reference to method of production
   - Ambiguous/complex language that could lead to confusion, misinterpretation, etc. (e.g. terms not agreed in Codex)
   - Use of consumer preference as the primary basis for setting international standards
   - Misleading the consumer on the nature of the products they buy.

8. These thematic issues were discussed extensively by the participants after which the facilitator divided them into four groups. He charged each of these groups to (a) develop a statement regarding the objective of a labelling text and (b) what would be the key indicators of success that such a text would reflect. A compilation of the outcomes of the group discussions is attached as Appendix 2. After the various groups reported back, the facilitator offered the following as a general compilation of an objective statement recognizing that it is neither a consensus objective nor does it seek to avoid inherent conflicts in some elements. Key factors of success were summarized, stressing that it was not intended to be considered a consensus text but merely a text that reflected the various views offered during the discussion:

   "Articulate guidance based upon existing Codex texts which can inform member countries national frameworks for the labelling of foods derived through modern biotechnology (FDMB):

   - ***Providing principles relevant to FDMB within the Codex framework for labelling all foods.***
   - ***Supporting informed choice by consumers***
   - ***Enabling different approaches to the national framework supporting the above"***

9. On the basis of the significant dialogue and exploration of objectives and considerations influencing the positions of the various delegations, the facilitated session considered the current text as contained in Appendix X to Alinorm 10/33/22, (Report of the 38th Session of the CCFL). To facilitate the discussion of the options regarding texts, participants were asked to consider adjustments that would focus on bridging various positions on the basis of four bridging principles:

- Avoid winners and losers
- Minimize value judgement elements
- Simple construction
- Neutrality

10. Before considering the chapeau statements, the participants considered the ten paragraphs contained in the text following the chapeau statements. It was suggested that the document should only reference the relevant Codex texts identified in paragraph 1 of the Appendix as well as the more specific sections of these texts which were identified in table 1. It was also suggested that the list of relevant Codex texts in paragraph 1 should be expanded to include the *Codex Guidelines for the Production, Packaging and Labelling of Organic Foods* and the *Guideline for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA Animals*.

11. A number of participants expressed concern that merely reproducing sections of the relevant texts might result in text being used out of context as these texts had been developed with a particular objective in mind. Others felt that principles reflected by only referencing Codex texts did not provide sufficient guidance for their needs. After some discussion, the participants recognized there were three possible approaches with regards to the above guidance and would provide these options for consideration by the 39th Session of the CCFL:

    (a) The guidance could make reference to the relevant texts in paragraph 1 of the Appendix with the addition of the *Codex Guidelines for the Production, Packaging and Labelling of Organic Foods* and the *Guideline for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA Animals* and include reference to particularly pertinent sections.
    (b) The guidance could make reference to the relevant texts found in paragraph 1 (with the addition of the *Codex Guidelines for the Production, Packaging and Labelling of Organic Foods* and the *Guideline for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA Animals*) and include reproductions of the relevant specific sections in table 1.
    (c) All relevant texts could be reproduced in the guidance document.

12. During the discussions of the chapeau statements, it was noted that the statements appeared to be a mix of identification of the purpose of the document as well as some principles. This contributed to confusion and ambiguity. Several delegations expressed the view that the chapeau statements were intended to be an introduction to the text that followed and hence needed to reflect the purpose of the document which might also include key considerations. It was also felt that the title of the document added to the confusion.

13. The facilitator led the group in an exercise to develop a common statement of purpose for the text and the articulation of key considerations. The objectives and success factors previously discussed, again served to underpin the exercise. Through this process, the session was able to assemble “Purpose” and “Considerations” text which it agreed should be considered by the 39th Session of CCFL and is reflected in each option under consideration.

14. It was not, however, possible to agree on a revised title to the text and instead three options were retained for further consideration.
15. Recognizing that full consensus was not achieved, it was viewed as a useful basis for consideration by the Committee. The participants therefore agreed to forward to the 39th Session of the CCFL for consideration the three possible options as outlined in Appendix 3 to this report.

Appendix 1

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15/16 NOVEMBER 2010
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Appendix 2

Compilation of Breakout Group Presentations

ENGLISH GROUP 1:

Provide direction/statement on how/that existing Codex texts can be used by countries to develop their national framework for foods derived from modern biotechnology.

Key Indicators:

Compilation of Codex texts

Members have adequate guidance

Mechanistic indicators – [FAO]?

ENGLISH GROUP 2:

1. To provide guidance to countries that want information on whether, and if so how, to label foods derived from modern biotechnology (FDMB).
2. To provide guidance consistent with existing Codex texts.
3. To assemble together texts of Codex that are useful in providing guidance for labelling of FDMB
4. Guidance on how FDMB could be known by consumers.

KEY INDICATORS:

1. Consistency with Codex texts
2. Consensus on approach
3. Utilization of the guidance document developed by CCFL
4. Facilitate promotion of fair practices in the food trade
5. Allows traceability of FDMB
6. Allows informed choice by consumers

GROUPE FRANCOPHONE:

Donner des lignes directives aux membres du Codex pour l'étiquetages des denrées alimentaires dérivées des biotechnologies sur la base des textes existants du Codex.

Indicateurs de succès :

- Prise en compte des textes existants
- Les principes établis ne doivent pas favoriser une approche par rapport à une autre
- Applicable/acceptable à l'échelle globale
- Respecte des 2 objectifs du Codex :
  - ✓ Protection de la santé du consommateur
  - ✓ Promotion de pratiques loyales dans le commerce internationale

GRUPO ESPAΨOL

The document should provide orientation regarding Codex guidelines, standards and principles related to foods derived from modern biotechnology, including those related to food labelling.

Document then could include a list of relevant Codex texts.

Indicators of success

(1) The document grouped after this objective fulfills the CAC mandate to CCFL.
(2) These documents have been approved by member states;
(3) These documents have a long standing enforcement period which leaves no doubt regarding ambiguity.
(4) As these texts are applicable to all foods, they are already including foods derived from modern biotechnology.
(5) This idea encompasses all the approaches related to labelling of foods derived from modern biotechnology.

Appendix 3

GUIDANCE TEXT OPTIONS

OPTION 1: (Reference to relevant texts)

Title:
[Proposed Draft Guidance regarding the Labelling of foods derived from Modern Biotechnology], or
[Proposed Draft Compilation of [references] Codex Labelling and other texts relevant to labelling foods derived from modern biotechnology], or
[Proposed Draft Guidance Drawn from Codex Texts relevant to the labelling of foods derived from modern biotechnology].

Purpose:
The purpose of this document is only to recall and assemble in a single document some important elements of guidance from Codex texts, which are relevant to labelling of foods derived from modern biotechnology.

Considerations:
Acknowledging that different approaches regarding labelling of foods derived from modern biotechnology are used, this document is not intended to suggest or imply that foods derived from modern biotechnology are necessarily different from other foods simply due to their method of production. Any framework implemented by Codex members should fully respect the already adopted Codex provisions

1. The following Codex standards and related texts contain provisions applicable to the labelling of food products and may be applied to foods obtained by GM/GE:]

- The Codex General Standard for the Labelling of Prepackaged Foods, (Codex Stan 1-1985); and particularly, Sections 3.1, 3.2, 4.1.1, 4.1.2, 4.2.2, 7.1
- The Codex General Guidelines on Claims (CAC/GL 1-1979); and particularly, Sections 1.2, 1.3, Section 2 – Definition of Claim, 3.3, 3.5, 4.1, 5.1(iii), 5.1(iv), 5.1(vi)
- The Codex Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997); Introduction and particularly, Sections 1.1, 1.2, 1.3, 1.4 and 1.5
- Principles for Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003); and particularly, Paragraph 19.
- Guidelines for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA plants (CAC/GL 45-2003)
- Guidelines for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA microorganisms (CAC/GL 46-2003)
- Working Principles for Risk Analysis for Food Safety for Application by Governments (CAC/GL 44-2003)
- Guideline for the Conduct of Food Safety Assessment of Foods derived from Recombinant-DNA Animals (CAC/GL 68-2008)
- The Codex Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CAC/GL 32-1999); and particularly Section 1.5

OPTION 2: (Reproduction of relevant texts current found in Table 1 of Appendix X of ALINORM 10/33/22)

Title:
[Proposed Draft Guidance regarding the Labelling of foods derived from Modern Biotechnology], or
[Proposed Draft Compilation of [references] Codex Labelling and other texts relevant to labelling foods derived from modern biotechnology], or
[Proposed Draft Guidance Drawn from Codex Texts relevant to the labelling of foods derived from modern biotechnology].

Purpose:
The purpose of this document is only to recall and assemble in a single document some important elements of guidance from Codex texts, which are relevant to labelling of foods derived from modern biotechnology.

Considerations:

Acknowledging that different approaches regarding labelling of foods derived from modern biotechnology are used, this document is not intended to suggest or imply that foods derived from modern biotechnology are necessarily different from other foods simply due to their method of production. Any framework implemented by Codex members should fully respect the already adopted Codex provisions

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- The Codex Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CAC/GL 32-1999)

Table 1. Provisions in existing Codex labelling texts that apply to the labeling of GM/GE foods

- *Codex General Standard for the Labelling of Prepackaged Foods*, (Codex Stan 1-1985)

✓ Section 3.1: Prepackaged foods shall not be described or presented on any label or in any labelling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect.

✓ Section 3.2: Prepackaged food shall not be described or presented on any label or in any labelling by words, pictorial or other devices which refer to or are suggestive either directly or indirectly, of any other product with which such food might be confused, or in such a manner as to lead the purchaser or consumer to suppose that the food is connected with such other product.

✓ Section 4.1.1: The name [of the food] shall indicate the true nature of the food and normally be specific and not generic.

✓ Section 4.1.2: There shall appear on the label either in conjunction with, or in close proximity to, the name of the food, such additional words or phrases as necessary to avoid misleading or confusing the consumer in regard to the true nature and physical condition of the food including but not limited to the type of packaging medium, style, and the condition or type of treatment it has undergone; for example, dried, concentrated, reconstituted, smoked.

✓ Section 4.2.2: The presence in any food or food ingredients obtained through biotechnology of an allergen transferred from any of the products listed in section 4.2.1.4 shall be declared. When it is not possible to provide adequate information on the presence of an allergen through labelling, the food containing the allergen should not be marketed.

✓ Section 7.1: Optional labelling – Any information or pictorial device written, printed, or graphic matter may be displayed in labelling provided that it is not in conflict with the mandatory requirements of this standard and those relating to claims and deception given in section 3 – General Principles.

- *Codex General Guidelines on Claims* (CAC/GL 1-1979)
  - ✓ Sections 1.2: The principle on which the guidelines are based is that no food should be described or presented in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect.
  - ✓ Section 1.3: The person marketing the food should be able to justify the claims made.
  - ✓ Section 2 – Definition of Claim - For the purpose of these guidelines, a claim is any representation which states, suggests, or implies that a food has particular characteristics relating to its origin, nutritional properties, nature, production, processing, composition or any other quality.

- ✓ Section 3.3: Prohibited claims – Claims which cannot be substantiated.
- ✓ Section 3.5: Prohibited claims – Claims which could give rise to doubt about the safety of similar food or which could arouse or exploit fear in the consumer.
- ✓ Section 4.1: Potentially misleading claims – Meaningless claims including incomplete comparatives and superlatives.
- ✓ Section 5.1(iii): Conditional claims – Terms such as "natural," "pure," "fresh," "home made," "organically grown," and "biologically grown" when they are used, should be in accordance with the national practices in the country where the food is sold. The use of these terms should be consistent with the prohibitions set out in Section 3.
- ✓ Section 5.1(iv): Conditional claims – Claims that a food has special characteristics when all such foods have the same characteristics, if this fact is apparent in the claim.
- ✓ Section 5.1(vi): Conditional claims – Claims which highlight the absence or non-addition of particular substances to food may be used provided that they are not misleading and provided that the substance:
  (b) is one which consumers would normally expect to find in the food;

  (d) is one whose presence or addition is permitted in the food

- *Codex Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997)
  - ✓ Introduction - Nutrition claims should be consistent with national nutrition policy and support that policy. Only nutrition claims that support national nutrition policy should be allowed. Health claims should be consistent with national health policy, including nutrition policy, and support such policies where applicable. Health claims should be supported by a sound and sufficient body of scientific evidence to substantiate the claim, provide truthful and non-misleading information to aid consumers in choosing healthful diets and be supported by specific consumer education. The impact of health claims on consumers' eating behaviours and dietary patterns should be monitored, in general, by competent authorities. Claims of the type described in section 3.4 of the Codex General Guidelines on Claims are prohibited
  - ✓ Section 1.1: These guidelines relate to the use of nutrition and health claims in food labelling and, where required by the authorities having jurisdiction, in advertising.
  - ✓ Section 1.2: These guidelines apply to all foods for which nutrition and health claims are made without prejudice to specific provisions under Codex standards or Guidelines relating to Foods for Special Dietary Uses and Foods for Special Medical Purposes.
  - ✓ Section 1.3: These guidelines are intended to supplement the Codex General Guidelines on Claims and do not supersede any prohibitions contained therein.
  - ✓ Section 1.4: Nutrition and health claims shall not be permitted for foods for infants and young children except where specifically provided for in relevant Codex standards or national legislation.

- *Principles for Risk Analysis of Foods Derived from Modern Biotechnology* (CAC/GL 44-2003);
  - ✓ Paragraph 19: Risk management measures may include, as appropriate, food labelling conditions for marketing approvals and post-market monitoring.

- *Guidelines for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA plants* (CAC/GL 45-2003)

- *Guidelines for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA microorganisms* (CAC/GL 46-2003)

- *Working Principles for Risk Analysis for Food Safety for Application by Governments* (CAC/GL 62-2007)

- *Guideline for the Conduct of Food Safety Assessment of Foods derived from Recombinant-DNA Animals* (CAC/GL 68-2008)

Codex Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CAC/GL 32-1999);

- ✓ Section 1.5: All materials and/or the products produced from genetically engineered/modified organisms (GEO/GMO) are not compatible with the principles of organic production (either

the growing, manufacturing, or processing) and therefore are not accepted under these guidelines.

OPTION 3: (Reproduction of all relevant texts.)

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- The Codex Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997);
- Principles for Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003);
- Guidelines for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA plants (CAC/GL 45-2003)
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- The Codex Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CAC/GL 32-1999);

Table 1. Provisions in existing Codex labelling texts that apply to the labeling of GM/GE foods

All the relevant texts from the above referenced documents would be reproduced here. In order to conserve paper, these texts are not reproduced in this report but this is an option being forwarded to the Committee for its consideration.